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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/441,242	11/16/99	RUSSO	G 8666-008-999

020583
PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

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EXAMINER	
SHUMAN, J	
ART UNIT	**PAPER NUMBER**
1636	3

DATE MAILED: 04/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 09/441,242	Applicant(s) Russo et al
	Examiner Jon Shuman	Group Art Unit 1636

☒ Responsive to communication(s) filed on *the preamendment of November 15, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *5-7, 11-19, 22-63, and 65* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *5-7, 11-19, 22-63, and 65* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 5-7, 13, 17, 18 and 19, drawn to a TCL-1 protein, a TCL-1 fusion protein, a method of making a TCL-1 protein, and proteins homologous to a TCL-1 protein, classified in class 530, subclass 350, class 435, subclass 69.1, and class 530, subclass 350, respectively.

II. Claims 22-28, 44, 45, and 57, drawn to methods of detecting a TCL-1 abnormality, and a method of diagnosis, classified in class 435, subclass 91.2, and class 435, subclass 6, respectively.

III. Claims 11, 12, 29 and 30, drawn to antisense nucleic acids to TCL-1, and the composition comprising the antisense nucleic acids , classified in class 536, subclass 24.5.

IV. Claims 14-16, 31 and 37-42, drawn to antibodies to a TCL-1 protein, the composition of the antibodies, and a method of detecting TCL-1 with antibodies, classified in class 530, subclass 387.1 and class 436, subclass 503, respectively.

V. Claims 32-36, 43 and 63, drawn to methods of detecting a target sequence, classified in class 536, subclass 23.1 and class 435, subclass 6.

VI. Claims 46-49, drawn to methods of treating a disease state, classified in class 514, subclass 44.

VII. Claims 50-54, drawn to methods of treatment using antibodies, classified in class 530, subclass 187.1.

VIII. Claims 55-56, drawn to oligonucleotide compositions, classified in class 536, subclass 24.31.

IX. Claims 58-62, drawn to methods of diagnosing a malignancy, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the proteins and methods of making proteins of group I are chemically distinct and procedurally distinct from the methods of detecting a TCL-1 abnormality, methods of diagnosis and the diagnostic kit of group II. The methods of the independent inventions are directed to distinct outcomes, the chemical structures of the macromolecules are unrelated and the functions of the marcromolecules are different. A search of the relevant literature would be neither overlapping nor coextensive, and would be burdensome.

3. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the antisense nucleic acids of group III and the antibodies and compositions of group

IV are chemically distinct. The independent inventions are classified differently, requiring different fields of search. In addition, they have different uses, for example, the antisense oligonucleotides can be used for in vitro gene expression studies. A search of the relevant literature would be neither overlapping nor coextensive, and would be burdensome.

4. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the method of detecting a target sequence, diagnostic kit, and nucleic acid compositions of the kit, group V, are distinct from the method of treating a disease state, group VI. The methods involve completely different procedural steps which are directed at different outcomes. The methods of group V are practiced *in vitro*, while the methods of group VI are practiced *in vivo*. The distinct inventions require different fields of search, a search of the relevant literature would be neither overlapping nor co-extensive, and would therefore be burdensome.

5. Inventions VII and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the method of treatment using the antibodies of group VII and the oligonucleotide compositions of Group VIII have distinct chemical structures and their uses are not related. The methods of treatment are practiced *in vivo*, while the oligonucleotides are used

in vitro, for example, as probes. The inventions are classified differently, a search of the relevant literature would be neither overlapping nor coextensive, and would therefore be burdensome.

6. Inventions IX and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, the methods of diagnosis using antibodies, Group IX, are a distinct invention relative to the proteins, fusion proteins, and methods of making proteins of Group I. The independent inventions have different tertiary structures and different biological functions, they are classified independently and require differing fields of search. A search of the relevant literature would be neither overlapping nor coextensive, and would be burdensome.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. A telephone call was made to Adriane Antler on April 10, 2000 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Shuman whose telephone number is (703) 306-5819. The examiner can normally be reached on Monday to Friday from 8:00 AM to 4:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached on (703) 308-4003. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Jon Shuman

April 11, 2000

DAVID GUZO
PRIMARY EXAMINER